



October 3, 2019

Atlas Medical
Amani Al-Habahbeh
Registration and RA Manager
P.O Box 204
King Abdullah Industrial Estate, Sahab free zone Area
Amman
Jordan

Re: k191099

Trade/Device Name: Atlas Multi-Drugs Screening Test Cup, Atlas Multi-Drugs Screening Test Panel
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, JXN, DIO, DJC, DJR, DJG, LCM, LDJ, LFG, DNK
Dated: May 9, 2019
Received: May 13, 2019

Dear Amani Al-Habahbeh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use**510(k) Number (if known)**

K191099

Device Name

Atlas Multi-Drugs Screening Test Cup

Atlas Multi-Drugs Screening Test Panel

Indications for Use (Describe)

Atlas Multi-Drugs Screening Test Cup and Atlas Multi-Drugs Screening Test Panel are lateral flow chromatographic in vitro diagnostics immunoassays for the qualitative detection of following drugs in urine without the need of instruments:

Drug Name	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	1000
Methylenedioxymethamphetamine (MDMA)	D,L Methylenedioxymethamphetamine	500
Morphine (MOP)	Morphine	300
Morphine (MOP)	Morphine	2000
Oxycodone (OXY)	Oxycodone	100
Cocaine (COC)	Benzoyllecgonine	300
Nortriptyline	Nortriptyline	1000
Methamphetamine (MET)	D-Methamphetamine	1000
Phencyclidine (PCP)	Phencyclidine	25
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	50
Secobarbital	Secobarbital	300
Oxazepam	Oxazepam	300
Methadone (MTD)	Methadone	300
Propoxyphene (PPX)	Propoxyphene	300
Buprenorphine(BUP)	Buprenorphine	10

The tests are intended for professional use only. The tests will yield preliminary positive results when the prescription drugs Secobarbital, oxazepam, Buprenorphine, Oxycodone, Propoxyphene, and Nortriptyline are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Secobarbital, oxazepam, Buprenorphine, Oxycodone, Propoxyphene, and Nortriptyline in urine. The multi-drugs screening tests (Cup and Panel formats) show the drug was or was not present at the cutoff level. The tests provide only preliminary test results, which must be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring the drug levels.

Type of Use (Select one or both, as applicable)☒ Prescription Use (Part 21 CFR 801 Subpart D)☐ Over-The-Counter Use (21 CFR 801 Subpart C)**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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510(k) Summary

1- Submitter name, Address, telephone number, contact person, and the date of the summary prepared:

The submitter's name: Atlas Medical.
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Amman 11512 Jordan.
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Email: quality.assurance3@atlas-medical.com
Contact person: Amani AL-Hababbeh
(Registration and RA Manager)

510 K number: K191099.

This 510(k) summary was prepared on October 01th, 2019.

2- The name of the device

Trade Name: Atlas Multi-Drugs Screening Test Panel
Atlas Multi-Drugs Screening Test Cup
Common Name: Drug of Abuse screening Tests
Classification Name: Immunoassay for the detection of drugs of abuse
Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DKZ	Class II	21 CFR 862.3100 Amphetamine Test System	91 (Toxicology)
DIS	Class II	21 CFR 862.3150 Barbiturate test system	91 (Toxicology)
JXM	Class II	21 CFR 862.3170 Benzodiazepine test system	91 (Toxicology)
JXN	Class II	21 CFR 862.3700 Propoxyphene Test System	91 (Toxicology)
DIO	Class II	21 CFR 862.3250 Cocaine and cocaine metabolite test system	91 (Toxicology)
DJC	Class II	21 CFR 862.3610 Methamphetamine test system	91 (Toxicology)
DJR	Class II	21 CFR 862.3620 Methadone test system	91 (Toxicology)
DJG	Class II	21 CFR 862.3650 Opiate test system	91 (Toxicology)

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LCM	Unclassified, Enzyme immunoassay, phencyclidine test system		91 (Toxicology)
LDJ	Class II	21 CFR 862.3870 Cannabinoid test system	91 (Toxicology)
LFG	Class II	21 CFR 862.3910 Tricyclic antidepressant drugs test system	91 (Toxicology)
DNK	Class II	21 CFR 862.3640 Morphine test system	91 (Toxicology)

Format: Cup and Panel Formats.

3- Equivalence legally marketed device:

Atlas Multi-Drugs Screening Tests (Cup and Panel Formats) has been determined to be substantially equivalent (Rapid Single/Multi-drug Test Cup, Rapid Single/Multi-drug Test Dipcard) (K 153050) currently in commercial distribution and manufactured by Co-innovation Biotech Co., ltd. (K153050).

4- Device description:

- 1) Atlas Multi-Drugs Screening Test cup format is single use device. The user collects urine in the cup to the recommended volume. The reaction is initiated by movement the sample to the strip. The strips are incorporated into the sides of sample cup.
- 2) Atlas Multi-Drugs Screening Test panel format is single use dip card device. The user inserts the absorbent end of the device in the urine sample to the maximum level indicated by the line on the device label. The test reaction is initiated by movement of the sample through the strip.

Atlas Multi-Drugs Screening Tests (Cup and Panel Formats) detect up to 14 drugs. The table presented below lists of detected drugs:

Drug Name	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	1000 ng/ml
Methylenedioxymethamphetamine (MDMA)	D,L Methylenedioxymethamphetamine	500 ng/ml
Morphine (MOP)	Morphine	300 ng/ml
Morphine (MOP)	Morphine	2000 ng/ml
Oxycodone (OXY)	Oxycodone	100 ng/ml
Cocaine (COC)	Benzoylecgonine	300 ng/ml
Nortriptyline	Nortriptyline	1000 ng/ml
Methamphetamine (MET)	D-Methamphetamine	1000 ng/ml
Phencyclidine (PCP)	Phencyclidine	25 ng/ml
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	50 ng/ml
Secobarbital	Secobarbital	300 ng/ml
Oxazepam	Oxazepam	300 ng/ml
Methadone (MTD)	Methadone	300 ng/ml

Propoxyphene (PPX)	Propoxyphene	300 ng/ml
Buprenorphine(BUP)	Buprenorphine	10 ng/ml

5- Intended use (Indication for use):

Atlas Multi-Screening Tests (Cup and panel formats) are lateral flow chromatographic in vitro diagnostics immunoassays for the qualitative detection of following drugs in urine without the need of instruments:

Drug Name	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	1000 ng/ml
Methylenedioxymethamphetamine (MDMA)	D,L Methylenedioxymethamphetamine	500 ng/ml
Morphine (MOP)	Morphine	300 ng/ml
Morphine (MOP)	Morphine	2000 ng/ml
Oxycodone (OXY)	Oxycodone	100 ng/ml
Cocaine (COC)	Benzoylcegonine	300 ng/ml
Nortriptyline	Nortriptyline	1000 ng/ml
Methamphetamine (MET)	D-Methamphetamine	1000 ng/ml
Phencyclidine (PCP)	Phencyclidine	25 ng/ml
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	50 ng/ml
Secobarbital	Secobarbital	300 ng/ml
Oxazepam	Oxazepam	300 ng/ml
Methadone (MTD)	Methadone	300 ng/ml
Propoxyphene (PPX)	Propoxyphene	300 ng/ml
Buprenorphine(BUP)	Buprenorphine	10 ng/ml

The tests are intended for professional use only. The tests will yield preliminary positive results when the prescription drugs Secobarbital, oxazepam, Buprenorphine, Oxycodone, Propoxyphene, and Nortriptyline are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Secobarbital, oxazepam, Buprenorphine, Oxycodone, Propoxyphene, and Nortriptyline in urine. The multi-drugs screening tests (Cup and Panel formats) show the drug was or was not present at the cutoff level. The tests provide only preliminary test results, which must be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring the drug levels.

6- Test Format:

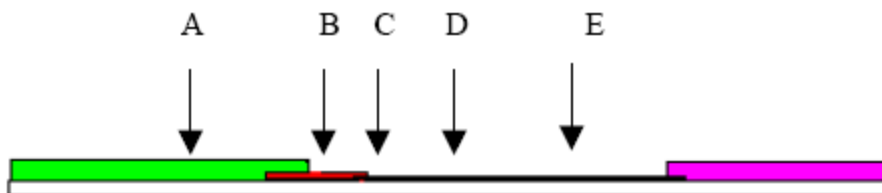
Atlas Multi-Drugs Screening Tests formats are Cup and panel.

7- Test Principle:

Atlas Multi-Drugs Screening Tests (Cup and panel formats) (Urine) are an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific

antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region. A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Figure 1: Test Principle



As shown in Figure 1 above, the specimen (A) migrates via capillary action along the membrane to react with the colored conjugate (B). Drugs present in the specimen below cutoff, will not saturate the binding sites of the gold-conjugated specific antibodies and not form a colored antibody-antigen complex(C). The gold-conjugated antibodies will then be captured by immobilized specific drug conjugate and a visible red band will form indicating a negative result (D). The absence of line formation in the test line region indicates a positive reading and that the drugs level of the test specimen is above the detection sensitivity of the test. In the control line region of the membrane, immobilized reagents capture colored conjugate regardless of the presence of the test specimen composition. The resulting visible red band (E) confirms that the assay is functioning correctly.

8- Major ingredients of Atlas Multi-Drugs Screening Tests (Cup and Panel formats):

- Goat antibody.
- Specific Drug antibody.
- Specific Drug conjugate.
- Adhesive plastic backing.
- Absorbant pad.

9- Comparison with predicate device

Feature Comparison of Atlas Multi-Drugs Screening Tests (Cup and Panel formats) with Rapid Single/Multi-drug Test Cup, Rapid Single/Multi-drug Test Dipcard currently in commercial distribution and manufactured by Co-innovation Biotech Co., ltd. (K153050).

Similarities		
Item	Device (Atlas Multi-Drugs Screening Test panel and Atlas Multi-Drugs Screening Test Cup)	Predicate (Rapid Single/Multi-drug Test Cup, Rapid Single/Multi-drug Test Dipcard) (K 153050)
Intended use	For the qualitative detection of drugs of abuse.	For the qualitative detection of drugs of abuse.
Specimen type (Matrix)	Urine	Urine
Indication for Use	Screening test for rapid detection of the drugs of abuse in urine.	Screening test for rapid detection of the drugs of abuse in urine.
Methodology	Colloidal Gold Immunoassay (Membrane particle assay)	Colloidal Gold Immunoassay (Membrane particle assay)
Test Time	5 minutes.	5 minutes.
Cut-off	AMP 1000 ng/ml	AMP 1000 ng/ml
	MDMA 500 ng/ml	MDMA 500 ng/ml
	Oxazepam 300 ng/ml	Oxazepam 300 ng/ml
	BUP 10 ng/ml	BUP 10 ng/ml
	COC 300 ng/ml	COC 300 ng/ml
	MET 1000 ng/ml	MET 1000 ng/ml
	MTD 300 ng/ml	MTD 300 ng/ml
	MOP 300 ng/ml	MOP 300 ng/ml
	MOP 2000 ng/ml	MOP 2000 ng/ml
	OXY 100 ng/ml	OXY 100 ng/ml
	PCP 25 ng/ml	PCP 25 ng/ml
	PPX 300 ng/ml	PPX 300 ng/ml
	Nortriptyline 1000 ng/ml	Nortriptyline 1000 ng/ml
	THC 50 ng/ml	THC 50 ng/ml
	Secobarbital 300 ng/ml	Secobarbital 300 ng/ml
Intender user	Professional users.	Professional users.

Differences		
Item	Device (Atlas Multi-Drugs Screening Test panel and Atlas Multi-Drugs Screening Test Cup).	Predicate (Rapid Single/Multi-drug Test Cup, Rapid Single/Multi-drug Test Dipcard). (K 153050).
Storage	2-30 °C	4-30 °C

10. Performance Characteristics:

1. Analytical performance:

a) Precision:

The study involved three users, each were given part of the prepared samples. Users were also given adequate number of Atlas Multi-Drugs Screening Tests (Cup and panel formats) from three different lots. Users were asked to test each sample with 15 tests from each format (Cup and panel formats); 5 tests on each lot and record the results in the designated table. The test was conducted as per the respective package inserts.

1.1 Atlas Multi-Drug Screening Test Panel Test Result:

Amphetamine (AMP) 1,000 ng/ml									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Secobarbital 300 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Oxazepam 300 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Buprenorphine (BUP) 10 ng/ml									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-

Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Marijuana (THC) 50 ng/ml									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Methadone (MTD) 300 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Methamphetamine (MET) 1,000 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Methylenedioxymethamphetamine (MDMA) 500 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Morphine (MOP) 300 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Morphine (MOP) 2000 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Oxycodone (OXY) 100ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-

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Phencyclidine (PCP) 25 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Propoxyphene (PPX) 300ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Nortriptyline 1,000 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Cocaine (COC) 300 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-

1.2 Atlas Multi-Drug Screening Test Cup Test Result:

Amphetamine (AMP) 1,000 ng/ml									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Secobarbital 300 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Oxazepam 300 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-

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Buprenorphine (BUP) 10 ng/ml									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Marijuana (THC) 50 ng/ml									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Methadone (MTD) 300 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Methamphetamine (MET) 1,000 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Methylenedioxymethamphetamine (MDMA) 500 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Morphine (MOP) 300 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Morphine (MOP) 2000 ng/mL									
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Oxycodone (OXY) 100ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-

Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Phencyclidine (PCP) 25 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Propoxyphene (PPX) 300ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Nortriptyline 1,000 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Cocaine (COC) 300 ng/mL									
Lot No.	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot A	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot B	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-
Lot C	45-/0+	45-/0+	45-/0+	45-/0+	45+/0-	45+/0-	45+/0-	45+/0-	45+/0-

Conclusion: The results above show that Atlas Multi-Drugs Screening Tests (Cup and Panel) formats are reproducible within lots, cross lots and cross users.

b) Analytical Sensitivity:

A drug-free urine pool was spiked with drugs to the concentrations at $\pm 50\%$ cut-off and $\pm 25\%$ cut-off. The samples were tested using Atlas Multi-Drugs Screening Tests (Cup and Panel). The results are summarized below.

1) Atlas Multi-Drug Screening Test Panel Test Result:

Drug conc. (Cut-off range)	n	AMP		BAR		BZO		BUP	
		-	+	-	+	-	+	-	+
Drug free	25	25	0	25	0	25	0	25	0
Cut-off-50%	25	25	0	25	0	25	0	25	0
Cut-off-25%	25	25	0	24	1	25	0	25	0
Cut-off+25%	25	0	25	0	25	0	25	0	25
Cut-off+50%	25	0	25	0	25	0	25	0	25

Drug conc. (Cut-off range)	n	COC		THC		MTD		MET	
		-	+	-	+	-	+	-	+
Drug free	25	25	0	25	0	25	0	25	0
Cut-off-50%	25	25	0	25	0	25	0	25	0
Cut-off-25%	25	25	0	24	1	25	0	25	0
Cut-off+25%	25	1	24	0	25	0	25	0	25
Cut-off+50%	25	0	25	0	25	0	25	0	25

Drug conc. (Cut-off range)	n	PCP		PPX		Nortriptyline	
		-	+	-	+	-	+
Drug free	25	25	0	25	0	25	0
Cut-off-50%	25	25	0	25	0	25	0
Cut-off-25%	25	25	0	24	1	25	0
Cut-off+25%	25	0	25	0	25	0	25
Cut-off+50%	25	0	25	0	25	0	25

Drug conc. (Cut-off range)	n	MDMA		MOP 300		MOP 2000		OXY	
		-	+	-	+	-	+	-	+
Drug free	25	25	0	25	0	25	0	25	0
Cut-off-50%	25	25	0	25	0	25	0	25	0
Cut-off-25%	25	25	0	25	0	25	0	25	0
Cut-off+25%	25	0	25	0	25	0	25	0	25
Cut-off+50%	25	0	25	0	25	0	25	0	25

2) Atlas Multi-Drug Screening Test Cup:

Drug conc. (Cut-off range)	n	AMP		BAR		BZO		BUP	
		-	+	-	+	-	+	-	+
Drug free	25	25	0	25	0	25	0	25	0
Cut-off-50%	25	25	0	25	0	25	0	25	0
Cut-off-25%	25	25	0	24	1	25	0	25	0
Cut-off+25%	25	0	25	0	25	0	25	0	25
Cut-off+50%	25	0	25	0	25	0	25	0	25

Drug conc. (Cut-off range)	n	COC		THC		MTD		MET	
		-	+	-	+	-	+	-	+
Drug free	25	25	0	25	0	25	0	25	0
Cut-off-50%	25	25	0	25	0	25	0	25	0
Cut-off-25%	25	25	0	24	1	25	0	25	0
Cut-off+25%	25	1	24	0	25	0	25	0	25
Cut-off+50%	25	0	25	0	25	0	25	0	25

Drug conc. (Cut-off range)	n	PCP		PPX		Nortriptyline	
		-	+	-	+	-	+
Drug free	25	25	0	25	0	25	0
Cut-off-50%	25	25	0	25	0	25	0
Cut-off-25%	25	25	0	24	1	25	0
Cut-off+25%	25	0	25	0	25	0	25
Cut-off+50%	25	0	25	0	25	0	25

Drug conc. (Cut-off range)	n	MDMA		MOP 300		MOP 2000		OXY	
		-	+	-	+	-	+	-	+
Drug free	25	25	0	25	0	25	0	25	0
Cut-off-50%	25	25	0	25	0	25	0	25	0
Cut-off-25%	25	25	0	25	0	25	0	25	0
Cut-off+25%	25	0	25	0	25	0	25	0	25
Cut-off+50%	25	0	25	0	25	0	25	0	25

Conclusion: As indicated in the table above: The Atlas Multi-Screening drugs tests (Cup and Panel) behave within their normal conditions as expected around their cut off values.

c) Analytical Specificity and Cross Reactivity:

Table below lists the compounds that are positively detected in urine by Atlas Drug of Abuse Rapid Tests (Cup and panel formats) (Urine) at 5 minutes and the concentrations at which they are detected.

1) Atlas Multi-Drug Screening Test Panel:

Drug Name		
AMPHETAMINE 1000 ng/mL	ng/mL	% of cross reactivity
D-Amphetamine	1000	100%
D,L-Amphetamine	2500	40%
L-Amphetamine	50000	2%
(+/-)3,4-Methylenedioxy-amphetamine (MDA)	2000	50%
Ephedrine	> 100000	>1%
3,4-Methylenedioxythylamphetamine (MDEA) +	> 100000	>1%
MDMA	1000	100%
D-Methamphetamine	1500	66.7%
L- Methamphetamine	3500	28.5%
Secobarbital 300 ng/mL	ng/mL	% of cross reactivity
Secobarbital	300	100%
Phenobarbital	2500	12%
Butalbital	500	60%
Pentobarbital	1500	20%
Amobarbital	2500	12%
Cyclopentobarbital	500	60%
Butethal	800	37.5%
Barbital	300	100%
Butabarbital	1500	20%

Buprenorphine 10 ng/mL	ng/mL	% of cross reactivity
Buprenorphine	10	100%
Norbuprenorphine	15	66.7%
Buprenorphine 3-D-Glucuronide	12.5	80%
Norbuprenorphine 3-D-Glucuronide	175	5.7%
Morphine-3-D-glucoronide	100000	0.01%
Morphine	> 100000	>0.01%
Oxymorphone	> 100000	>0.01%
Hydromorphone	> 100000	>0.01%

Oxazepam 300 ng/mL	ng/mL	% of cross reactivity
Oxazepam	300	100%
Alprazolam	200	150%
α -Hydroxyalprazolam	1000	30%

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Bromazepam	250	120%
Chlordiazepoxide	2500	12%
Clobazam	100	300%
Clonazepam	850	35.3%
Clorazepate	250	120%
Delorazepam	1600	18.75%
Diazepam	200	150%
Estazolam	200	150%
Flunitrazepam	300	100%
Lorazepam	1000	30%
Midazolam	1500	20%
Nitrazepam	100	300%
Nordiazepam	400	75%
Temazepam	150	200%
Triazolam	500	60%

COCAINE 300 ng/mL	ng/mL	% of cross reactivity
Cocaine	> 100000	>0.3%
Benzoylecgonine	300	100%
EcgonineHCl	35000	0.86%
Coaethylene	14000	2.14%
Norcocaine	> 100000	>0.3%
METHADONE 300 ng/mL	ng/mL	% of cross reactivity
Methadone	300	100%
(+)-2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium	50000	0.6%
Doxylamine	50000	0.6%
EMDP (2-Ethyl-5-methyl-3,3-diphenylpyrroline)	> 100000	>0.3%
LAAM (1-Alpha-acetylmethadol)	5000	6%
α - Methadol	2000	15%
Disopyramide	8000	3.75%

METHAMPHETAMINE 1000 ng/mL	ng/mL	% of cross reactivity
(+/-)- Methamphetamine	2000	50%
(+)-Methamphetamine	1000	100%
3,4-Methylenedioxythylamphetamine (MDEA)	35000	2.85%
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2000	50%
Ranitidine (Zantac)	> 100000	>1%

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3,4-Methylenedioxyamphetamine (MDA)	> 100000	>1%
D-Amphetamine	> 100000	>1%
L-Amphetamine	> 100000	>1%
Ephedrine	> 100000	>1%
L-Methamphetamine	5000	20%

METHYLENEDIOXYMETHAMPHETAMINE (MDMA) 500 ng/mL	ng/mL	% of cross reactivity
(+/-) 3,4-Methylenedioxyamphetamine (MDMA)	500	100%
D-Amphetamine	> 100000	> 0.5%
L-Methamphetamine	100000	0.5%
3,4-Methylenedioxyamphetamine (MDEA)	200	250%
3,4-Methylenedioxyamphetamine (MDA)	2000	25%
L-Amphetamine	> 100000	> 0.5%
D-Methamphetamine	> 100000	> 0.5%

MARIJUANA 50 ng/mL	ng/mL	% of cross reactivity
11-nor-D ⁹ -THC-9 COOH	50	100%
11-nor-D ⁸ -THC-9 COOH	50	100%
D ⁸ -THC	8000	0.6%
D ⁹ -THC	10000	0.5%
Cannabinol	100000	0.05%

MORPHINE 2000 ng/mL	ng/mL	% of cross reactivity
Morphine	2000	100%
Codeine	2000	100%
Hydrocodone	10000	20%
Hydromorphone	7000	28.5%
Morphine 3-b-D-glucuronide	2000	100%
6-Monoacetylmorphine	5000	40%
Normorphine	100000	2%
Oxycodone	20000	10%
Oxymorphone	100000	2%
Thebaine	70000	2.8%
Heroin	2500	80%
Ethylmorphine	5000	40%

MORPHINE 300 ng/mL	ng/mL	% of cross reactivity
Morphine	300	100%
Codeine	300	100%
Hydrocodone	2000	15%
Hydromorphone	3500	8.5%
Morphine 3-b-D-glucuronide	300	100%
6-Monoacetylmorphine	600	50%
Normorphone	100000	0.3%
Oxycodone	10000	3%
Oxymorphone	50000	0.6%
Thebaine	7000	4.3%
Heroin	350	85.7%
Ethylmorphine	6000	5%

OXYCODONE 100 ng/mL	ng/mL	% of cross reactivity
Oxycodone	100	100%
Morphine	50000	0.2%
Codeine	25000	0.4%
Morphine 3-b-D-glucuronide	50000	0.2%
Hydrocodone	1600	6.25%
Hydromorphone	15000	0.67%
Normorphone	100000	0.1%
Oxymorphone	1500	6.7%
6-Monoacetylmorphine	>100000	>0.1%
Ethylmorphine	5000	2%

PHENCYCLIDINE 25 ng/mL	ng/mL	% of cross reactivity
Phencyclidine	25	100%
4-Hydroxyphencyclidine	15000	0.17%

PROPOXYPHENE 300 ng/mL	ng/mL	% of cross reactivity
propoxyphene	300	100%
Norpropoxyphene	7500	4%
Methadone	> 100000	0.3%

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Notriptyline 1000 ng/mL	ng/mL	% of cross reactivity
Notriptyline	1000	100%
Trimipramine	4500	22.2%
Amitriptyline	1000	100%
Promazine	3000	33.3%
Desipramine	1000	100%
Imipramine	1000	100%
Clomipramine	7500	13.3%
Doxepine	3000	33.3%
Maprotiline	50000	2%

2) Atlas Multi-Drug Screening Test Cup:

Drug Name		
AMPHETAMINE 1000 ng/mL	ng/mL	% of cross reactivity
D-Amphetamine	1000	100%
D,L-Amphetamine	2500	40%
L-Amphetamine	50000	2%
(+/-)3,4-Methylenedioxy-amphetamine (MDA)	2000	50%
Ephedrine	> 100000	>1%
3,4-Methylenedioxythylamphetamine (MDEA) +	> 100000	>1%
MDMA	1000	100%
D-Methamphetamine	1500	66.7%
L- Methamphetamine	3500	28.5%

Secobarbital 300 ng/mL	ng/mL	% of cross reactivity
Secobarbital	300	100%
Phenobarbital	2500	12%
Butalbital	500	60%
Pentobarbital	1500	20%
Amobarbital	2500	12%
Cyclopentobarbital	500	60%
Butethal	800	37.5%
Barbital	300	100%
Butabarbital	1500	20%

Buprenorphine 10 ng/mL	ng/mL	% of cross reactivity
Buprenorphine	10	100%
Norbuprenorphine	15	66.7%
Buprenorphine 3-D-Glucuronide	12.5	80%
Norbuprenorphine 3-D-Glucuronide	175	5.7%
Morphine-3-D-glucoronide	100000	0.01%
Morphine	> 100000	>0.01%
Oxymorphone	> 100000	>0.01%
Hydromorphone	> 100000	>0.01%

Oxazepam 300 ng/mL	ng/mL	% of cross reactivity
Oxazepam	300	100%
Alprazolam	200	150%
α -Hydroxyalprazolam	1000	30%
Bromazepam	250	120%
Chlordiazepoxide	2500	12%
Clobazam	100	300%
Clonazepam	850	35.3%
Clorazepate	250	120%
Delorazepam	1600	18.75%
Diazepam	200	150%
Estazolam	200	150%
Flunitrazepam	300	100%
Lorazepam	1000	30%
Midazolam	1500	20%
Nitrazepam	100	300%
Nordiazepam	400	75%
Temazepam	150	200%
Triazolam	500	60%

COCAINE 300 ng/mL	ng/mL	% of cross reactivity
Cocaine	> 100000	>0.3%
Benzoyllecgonine	300	100%
EcgonineHCl	35000	0.86%
Coaethylene	14000	2.14%
Norcocaine	> 100000	>0.3%

METHADONE 300 ng/mL	ng/mL	% of cross reactivity
Methadone	300	100%
(±)2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium	50000	0.6%
Doxylamine	50000	0.6%
EMDP (2-Ethyl-5-methyl-3,3-diphenylpyrroline)	> 100000	>0.3%
LAAM (1-Alpha-acetylmethadol)	5000	6%
α- Methadol	2000	15%
Disopyramide	8000	3.75%

METHAMPHETAMINE 1000 ng/mL	ng/mL	% of cross reactivity
(+/-)- Methamphetamine	2000	50%
(+)-Methamphetamine	1000	100%
3,4-Methylenedioxythylamphetamine (MDEA)	35000	2.85%
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2000	50%
Ranitidine (Zantac)	> 100000	>1%
3,4-Methylenedioxyamphetamine (MDA)	> 100000	>1%
D-Amphetamine	> 100000	>1%
L-Amphetamine	> 100000	>1%
Ephedrine	> 100000	>1%
L-Methamphetamine	5000	20%

METHYLENEDIOXYMETHAMPHETAMINE (MDMA) 500 ng/mL	ng/mL	% of cross reactivity
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
D-Amphetamine	> 100000	> 0.5%
L-Methamphetamine	100000	0.5%
3,4-Methylenedioxythylamphetamine (MDEA)	200	250%
3,4-Methylenedioxyamphetamine (MDA)	2000	25%
L-Amphetamine	> 100000	> 0.5%
D-Methamphetamine	> 100000	> 0.5%

MARIJUANA 50 ng/mL	ng/mL	% of cross reactivity
11-nor-D ⁹ -THC-9 COOH	50	100%
11-nor-D ⁸ -THC-9 COOH	50	100%
D ⁸ -THC	8000	0.6%

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D ⁹ -THC	10000	0.5%
Cannabinol	100000	0.05%

MORPHINE 2000 ng/mL	ng/mL	% of cross reactivity
Morphine	2000	100%
Codeine	2000	100%
Hydrocodone	10000	20%
Hydromorphone	7000	28.5%
Morphine 3-b-D-glucuronide	2000	100%
6-Monoacetylmorphine	5000	40%
Normorphone	100000	2%
Oxycodone	20000	10%
Oxymorphone	100000	2%
Thebaine	70000	2.8%
Heroin	2500	80%
Ethylmorphine	5000	40%

MORPHINE 300 ng/mL	ng/mL	% of cross reactivity
Morphine	300	100%
Codeine	300	100%
Hydrocodone	2000	15%
Hydromorphone	3500	8.5%
Morphine 3-b-D-glucuronide	300	100%
6-Monoacetylmorphine	600	50%
Normorphone	100000	0.3%
Oxycodone	10000	3%
Oxymorphone	50000	0.6%
Thebaine	7000	4.3%
Heroin	350	85.7%
Ethylmorphine	6000	5%

OXYCODONE 100 ng/mL	ng/mL	% of cross reactivity
Oxycodone	100	100%
Morphine	50000	0.2%
Codeine	25000	0.4%
Morphine 3-b-D-glucuronide	50000	0.2%

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Hydrocodone	1600	6.25%
Hydromorphone	15000	0.67%
Normorphone	100000	0.1%
Oxymorphone	1500	6.7%
6-Monoacetylmorphine	>100000	>0.1%
Ethylmorphine	5000	2%

PHENCYCLIDINE 25 ng/mL	ng/mL	% of cross reactivity
Phencyclidine	25	100%
4-Hydroxyphencyclidine	15000	0.17%

PROPOXYPHENE 300 ng/mL	ng/mL	% of cross reactivity
propoxyphene	300	100%
Norpropoxyphene	7500	4%
Methadone	> 100000	0.3%

Nortriptyline 1000 ng/mL	ng/mL	% of cross reactivity
Nortriptyline	1000	100%
Trimipramine	4500	22.2%
Amitriptyline	1000	100%
Promazine	3000	33.3%
Desipramine	1000	100%
Imipramine	1000	100%
Clomipramine	7500	13.3%
Doxepine	3000	33.3%
Maprotiline	50000	2%

Conclusion: Atlas Multi-Drugs screening Tests (Cup and Panel formats) gave similar result behavior to positive results when tested with the previous mentioned substances at their corresponding concentration in the table. Where results found to be negative even at high concentrations, the above table reports the concentrations as >100,000ng/ml.

d) Interference (Interfering Substances):

The Drug-free urine samples were collected. Each sample had been spiked with drugs to the concentrations cut-off-25%, cut-off and cut-off+25%. These urine samples had been spiked with 100ug/ml of the various ingestible or physiological substances (albumin was evaluated at 20 mg/mL) using Atlas Multi-Drugs screening tests ((Cup and Panel formats).

The obtained results showed that the following list of substances showed no interference at the concentration 100 ug/ml(albumin was evaluated at 20 mg/mL) when tested with Atlas Multi-Drugs Screening Test Panel and Atlas Multi-Drugs Screening Test cup.

Acetophenetidin	Estrone-3-sulfate	Penicillin-G
Acetone	Ethyl alcohol	Perphenazine
N-Acetylprocainamide	L-ψ-Ephedrine	Phenelzine
Acetylsalicylic acid	Fenoprofen	L-Phenylephrine
Acetaminophen	Furosemide	b-Phenylethylamine
Albumin	Gentisic acid	Pheniramine
Aminopyrine	d-Glucose	Phenothiazine
Amoxicillin	Guaiacol Glyceryl Ether	Prednisolone
Ampicillin	Hemoglobin	Prednisone
L-Ascorbic acid	Hydralazine	Procaine
Apomorphine	Hydrochlorothiazide	DL-Propranolol
Aspartame	Hydrocortisone	D-Pseudoephedrine
Atropine	O-Hydroxyhippuric acid	Quinidine
Benzilic acid	Ibuprofen	Quinine
Benzoic acid	D,L--Isoproterenol	Ranitidine
Bilirubin	Isoxsuprine	Riboflavin
Caffeine	Ketamine	Salicylic acid
Cannabidiol	Ketoprofen	Serotonin
Chloralhydrate	Labetalol	Sodium chloride
Chloramphenicol	Lidocaine	Sulfamethazine
Chlorothiazide	Loperamide	Sulindac
(+)Chlorpheniramine	Meperidine	Tetracycline
Chlorprothixene	Meprobamate	Tetrahydrocortisone, 3-acetate
Chloroquine	Methoxyphenamine	Tetrahydrozoline
Cholesterol	Methylphenidate	Thiamine
Clonidine	Nalidixic acid	Theophylline
Cortisone	Naloxone	Tolbutamide
L- Cotine	Naltrexone	Triamterene
Creatinine	Naproxen	Trifluoperazine
Deoxycorticosterone	Niacinamide	Trimethoprim
Dextromethorphan	Nifedipine	DL-Tryptophan
Dexbrompheniramine	Nicotine	Verapamil
Diclofenac	Norethindrone	Zomepirac
Diffunisal	Noscapine	(R,2S)-(-)-N-Methyl-Ephedrine
Digoxin	Norephedrine	
4-Dimethylaminoantipyrine	d,l-Octopamine	
Diphenhydramine	Oxalic acid	

Dopamine	Oxolinic acid	
Erythromycin	Oxymetazoline	
b-Estradiol	Papaverine	

f) Effect of PH on Atlas Multi-Drugs Screening Tests (Cup and Panel):

The Drug-free urine samples were collected and tested by GC/MS or LC/MS to ensure they are drug free. These samples were spiked with drugs to the concentrations at $\pm 50\%$ cut-off and $\pm 25\%$ cut-off. The PH of these samples was adjusted to be 4.5, 5,6,7,8 and 9, respectively. The Cup and panel formats with all drug test strips were tested at each PH. The results demonstrated that the PH does not affect the results of Atlas Multi-Drugs screening tests (Cup and Panel) Formats.

g) Effect of specific gravity on Atlas Multi-Drugs Screening Tests (Cup and Panel):

The Drug-free urine samples were collected and tested by GC/MS or LC/MS to they are drug free. These samples were spiked with drugs to the concentrations at $\pm 50\%$ cut-off and $\pm 25\%$ cut-off. The specific gravity of these samples adjusted to be 1.005, 1.010, 1.015, 1.025 and 1.030, respectively. The Cup and panel formats with all drug test strips were tested at each specific gravity. The results demonstrated that the specific gravity do not affect the results of Atlas Multi-Drugs screening tests (Cup and Panel) Formats.

h) Clinical Study (Method Comparison):

The comparison study was conducted to compare Atlas Multi-Drugs screening Tests (Cup and panel formats) (Urine) with the GC/MS or LC/MS methods. Testing was performed on 80 Clinical specimens All samples used in this study belong to adults (males and females) with ages 18+. Samples were used as is without any dilution or alteration (except PCP samples which were diluted as per the table mentioned below in the study due to difficulty in sourcing PCP real samples). The unaltered clinical samples had been confirmed with Gas Chromatography Method (GC/MS) and the unaltered clinical samples (less than -50% of the cutoff, near cutoff negative (between -50% and the cutoff), near cutoff positive (between cutoff and +50%) and high positive (greater than +50%) were tested using Atlas Multi-Drugs screening Tests (Cup and panel formats) (Urine). Test results per drug are summarized in the table below:

1) Atlas Multi-Drugs screening Panel Test Result:

Tested Drug	Candidate Device Result	Negative samples	Less than half the cutoff concentration By GC/MS	Near cutoff negative (between -50% below the cutoff and the cutoff concentration)	Near cutoff positive (between the cutoff and +50% Above the cutoff concentration)	High Positive (greater than +50% above the cutoff concentration)
AMP 1000 ng/ml	Positive	0	0	1	4	36
	Negative	16	20	3	0	0

Secobarbital 300 ng/ml	Positive	0	0	1	2	37
	Negative	18	17	4	1	0
Oxazepam 300 ng/ml	Positive	0	0	2	3	36
	Negative	19	17	2	1	0
COC 300 ng/ml	Positive	0	0	1	3	37
	Negative	20	15	4	0	0
THC 50 ng/ml	Positive	0	0	0	2	36
	Negative	21	15	4	2	0
MTD 300 ng/ml	Positive	0	0	1	2	37
	Negative	18	17	4	1	0
MET 1000 ng/ml	Positive	0	0	2	3	36
	Negative	22	14	2	1	0
MDMA 500 ng/ml	Positive	0	0	1	4	36
	Negative	25	11	3	0	0
MOP 300 ng/ml	Positive	0	0	1	2	37
	Negative	21	14	4	1	0
MOP 2000 ng/ml	Positive	0	0	0	4	35
	Negative	20	17	3	1	0
PPX 300 ng/ml	Positive	0	0	1	2	36
	Negative	25	11	3	2	0
OXY 100 ng/ml	Positive	0	0	1	3	37
	Negative	21	14	4	0	0
Nortriptyline 1000 ng/ml	Positive	0	0	0	2	36
	Negative	22	14	4	2	0
BUP 10 ng/ml	Positive	0	0	0	2	36
	Negative	21	15	4	2	0
PCP 25 ng/ml	Positive	0	0	2	3	16
	Negative	20	16	4	0	0

2) Atlas Multi-Drugs screening Cup Test Result:

Tested Drug	Candidate Device Result	Negative samples	Less than half the cutoff concentration By GC/MS	Near cutoff negative (between - 50% below the cutoff and the cutoff concentration	Near cutoff positive (between the cutoff and +50% Above the cutoff concentration)	High Positive (greater than +50% above the cutoff concentration)
AMP 1000 ng/ml	Positive	0	0	1	4	36
	Negative	16	20	3	0	0
Secobarbital 300 ng/ml	Positive	0	0	1	2	37
	Negative	18	17	4	1	0
Oxazepam 300 ng/ml	Positive	0	0	2	3	36
	Negative	19	17	2	1	0

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COC 300 ng/ml	Positive	0	0	1	3	37
	Negative	20	15	4	0	0
THC 50 ng/ml	Positive	0	0	0	2	36
	Negative	21	15	4	2	0
MTD 300 ng/ml	Positive	0	0	1	2	37
	Negative	18	17	4	1	0
MET 1000 ng/ml	Positive	0	0	2	3	36
	Negative	22	14	2	1	0
MDMA 500 ng/ml	Positive	0	0	1	4	36
	Negative	25	11	3	0	0
MOP 300 ng/ml	Positive	0	0	1	2	37
	Negative	21	14	4	1	0
MOP 2000 ng/ml	Positive	0	0	0	4	35
	Negative	20	17	3	1	0
PPX 300 ng/ml	Positive	0	0	1	2	36
	Negative	25	11	3	2	0
OXY 100 ng/ml	Positive	0	0	1	3	37
	Negative	21	14	4	0	0
Nortriptyline 1000 ng/ml	Positive	0	0	0	2	36
	Negative	23	13	4	2	0
BUP 10 ng/ml	Positive	0	0	0	2	36
	Negative	21	15	4	2	0
PCP 25 ng/ml	Positive	0	0	2	3	16
	Negative	20	16	4	0	0

The Summary of Discordant Results is listed in the table below:

Assay	Cut-off	Sample Number	LC/MS Result	Atlas Multi – Screening DOA panel Test Results	Atlas Multi – Screening DOA Cup Test Results
AMP	1000ng/ml	Sample 23	855 ng/ml	Positive	Positive
Secobarbital	300 ng/ml	Sample 51	287 ng/ml	Positive	Positive
Secobarbital	300 ng/ml	Sample 71	348 ng/ml	Negative	Negative
Oxazepam	300 ng/ml	Sample 16	330 ng/ml	Negative	Negative
Oxazepam	300 ng/ml	Sample 37	299 ng/ml	Positive	Positive
Oxazepam	300 ng/ml	Sample 78	198 ng/ml	Positive	Positive
COC	300 ng/ml	Sample 67	294 ng/ml	Positive	Positive
THC	50 ng/ml	Sample 43	55 ng/ml	Negative	Negative
THC	50 ng/ml	Sample 66	56 ng/ml	Negative	Negative
MTD	300 ng/ml	Sample 43	304 ng/ml	Negative	Negative
MTD	300 ng/ml	Sample 80	293 ng/ml	Positive	Positive
MET	1000 ng/ml	Sample 6	1006 ng/ml	Negative	Negative
MET	1000 ng/ml	Sample 34	992 ng/ml	Positive	Positive
MET	1000 ng/ml	Sample 63	989 ng/ml	Positive	Positive

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MDMA	500 ng/ml	Sample 43	501 ng/ml	Positive	Positive
MOP	300 ng/ml	Sample 7	318 ng/ml	Negative	Negative
MOP	300 ng/ml	Sample 57	292 ng/ml	Positive	Positive
MOP	2000 ng/ml	Sample 4	2007 ng/ml	Negative	Negative
PCP	25 ng/ml	Sample 10	24 ng/ml	Positive	Positive
PCP	25 ng/ml	Sample 26	22 ng/ml	Positive	Positive
PPX	300 ng/ml	Sample 15	314 ng/ml	Negative	Negative
PPX	300 ng/ml	Sample 42	302 ng/ml	Negative	Negative
PPX	300 ng/ml	Sample 47	289 ng/ml	Positive	Positive
OXY	100 ng/ml	Sample 25	98 ng/ml	Positive	Positive
Nortriptyline	1000 ng/ml	Sample 61	1010 ng/ml	Negative	Negative
Nortriptyline	1000 ng/ml	Sample 78	1013 ng/ml	Negative	Negative
BUP	10 ng/ml	Sample 3	11 ng/ml	Negative	Negative
BUP	10 ng/ml	Sample 78	11 ng/ml	Negative	Negative

Note: Two Samples of high PCP concentration confirmed by GC/MS to be (192 ng/ml and 147 ng/ml) were collected; those samples were diluted with negative urine sample confirmed negative by GC/MS or LC/MS methods to make the following concentrations:

Table #1:

Sample #1	Sample #2
192 ng/ml	147 ng/ml
171 ng/ml	132 ng/ml
153 ng/ml	117 ng/ml
134 ng/ml	102 ng/ml
115 ng/ml	88 ng/ml
96 ng/ml	73 ng/ml
76 ng/ml	58 ng/ml
57 ng/ml	44 ng/ml
38 ng/ml	29 ng/ml
28 ng/ml	22 ng/ml
24 ng/ml	18 ng/ml
19 ng/ml	14 ng/ml
14 ng/ml	10 ng/ml
9 ng/ml	7 ng/ml
4 ng/ml	3 ng/ml
2 ng/ml	1 ng/ml
1 ng/ml	<1 ng/ml

High positive: 16

Near positive: 3

Near Negative: 6

Negative: 9

The cohort also uses 27 other negative urine samples confirmed by GC/MS or LC/MS methods.

Conclusion:

The Summary of % agreement of Atlas Multi-screening DOA Tests (Panel and Cup) formats with GC/MS method is listed in the table below:

Drugs	Cutoff	% Agreement Among positive	% Agreement Among negative
AMP	1000 ng/ml	100%	98%
Secobarbital	300 ng/ml	98%	98%
Oxazepam	300 ng/ml	98%	95%
COC	300 ng/ml	100%	98%
THC	50 ng/ml	95%	100%
MTD	300 ng/ml	98%	98%
MET	1000 ng/ml	98%	95%
MDMA	500 ng/ml	100%	98%
MOP	300 ng/ml	98%	98%
MOP	2000 ng/ml	98%	100%
PPX	300 ng/ml	95%	98%
OXY	100 ng/ml	100%	98%
Nortriptyline	1000 ng/ml	95%	100%
BUP	10 ng/ml	100%	95%
PCP	25 ng/ml	100%	95%

The obtained data from this study show that Atlas Multi-Drugs screening Tests (Cup and panel formats) (Urine) have relatively high sensitivity, Specificity and accuracy when compared to GS/MS or LC/MS methods.

I) Stability Study:**1) Real Time Stability**

Real Time Stability of the Drug of abuse rapid test was evaluated using samples from three different lots. These samples were placed in an incubator with the temperature calibrated at 2 ± 1 °C and 30 ± 1 °C with relative humidity (RH) calibrated at $60\pm3\%$. A series of stability tests were performed each month from 0 to 24 months. Tests were assayed using urine specimens with the drugs concentrations of 0% Cut-off, -25% Cut-off, -50% Cut-off, +25% Cut-off, +50% Cut-off. Results are read at 5 minute. The tests were performed according to the package insert.

Conclusion: Atlas Drug of Abuse Test Panel (Urine) is stable at the temperature of 2-30°C for 24 months.

2) Accelerated Stability

Accelerated Stability of the Drug of abuse rapid test was evaluated using samples from three different lots. These samples were placed in an incubator with the temperature calibrated at 40 ± 1 °C with relative humidity (RH) calibrated at $60\pm3\%$. A series of stability tests were performed each week from 0 to 3 weeks (4 weeks in total). Tests were assayed using urine specimens with drugs concentrations of 0% Cut-off, -25% Cut-off, -50% Cut-off, +25% Cut-off, +50% Cut-off. Results are read at 5 minute. The tests were performed according to the package insert.

Conclusion: Based on accelerated testing equations where one week represents one year of stability at room temperature Atlas Drug of abuse test is expected to be stable for at least 24 months.

L) Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR part 809.10.